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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|----------------|----------------------|-------------------------|-----------------|
| 09/899,303 | 07/06/2001 | Geert Maertens | 2752-52 | 3515 |
| 7. | 590 07/25/2002 | | | |
| NIXON & VANDERHYE P.C. 8th Floor 1100 North Glebe Road | | | EXAMINER | |
| | | | LI, BAO Q | |
| Arlington, VA | 22201-4714 | | ART UNIT PAPER NUMBER | |
| | | | 1648 | <i>a</i> |
| | | | DATE MAILED: 07/25/2002 | 9 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Applicati n N . | Applicant(s) | | | | |
|---|---|-------------------------|---|--|--|--|--|
| | | 09/899,303 | MAERTENS ET AL. | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | Bao Qun Li | 1648 | | | | |
| Period fo | The MAILING DATE of this c mmunication appears n the cover sheet with the correspond nce address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 12 D | December 2001 . | | | | | |
| 2a) <u></u> | | s action is non-final. | | | | | |
| 3) | | | | | | | |
| Disposit | Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) 67-94 is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) | Claim(s) is/are allowed. | | | | | | |
| 6) | 6) Claim(s) is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 67-94 are subject to restriction and/or election requirement. | | | | | | | |
| Application Papers | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10)[| The drawing(s) filed on is/are: a)□ accep | • | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11)[| The proposed drawing correction filed on | | ved by the Examiner. | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| * 5 | 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | | | | |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | |
| Attachment(s) | | | | | | | |
| 2) 🔲 Notic | ee of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal P | (PTO-413) Paper No(s) atent Application (PTO-152) | | | | |
| 0.0-1-1-1- | | | | | | | |

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DETAILED ACTION

Claims 67-94 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121:

- I. Claims 67-74, 76, 79 and 85-91, drawn to a recombinant vector comprising the HCV envelope protein, classified in class 430, subclass 320.1.
- II. Claim 75, drawn to a recombinant vector comprising a specific heterologous sequence, classified in class 424, subclass 185.1.

Upon election one of group II, Applicants are required to elect one single sequence from SEQ ID NO: 3, 5, 7, 9, 11, 13, 21, 23, 25, 27, 29, 31, 35, 37, 39, 41, 43, 45, 47 and 49 for the examination on the merits. This is not the species election because each single sequence has different structure and function.

- III Claims 77-78, drawn to a vaccine and method for using the vaccine to vaccinating human, classified in class 424, subclass 228.1.
- IV. Claims 80-83, 92-94, drawn to a host cell and a recombinant protein produced by the host cell, classified in class 435, subclass 325.

Upon election any one of group I or IV, Applicants are required to elect one single recombinant envelope from (i). E1, (ii). E2, (iii), E1 and E2, (iv). E1/E2, (v), E1, E2, plus E1/E for the examination on the merits. This is not the species election because each region of the envelope has different structure and produce different functions.

V. Claim 84, drawn to a method for purifying HCV envelope protein, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally and functionally different products e.g. the product of group I is a vector comprising the envelope protein of HIV, whereas the product of Group IV is a host cell.

Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make other material different product, such as fusion protein of HCV Non-structural protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

July 24, 2002

Boroganhi'

ALI R. SALIMI PRIMARY EXAMINER